THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PAMELA C. SHELP and SCOTT R. SHELP, Plaintiffs, v. ALLERGAN, INC., *et al.* Defendants.	CASE NO. C18-1427-JCC ORDER

This matter comes before the Court on Defendant Mentor Worldwide, LLC's ("Mentor") unopposed[1] motion to dismiss (Dkt. No. 20). Having thoroughly considered Mentor's briefing and the relevant record, the Court finds oral argument unnecessary and hereby GRANTS the motion for the reasons explained herein.

I. BACKGROUND

In 2011, Plaintiff Pamela Shelp underwent breast augmentation surgery. (Dkt. No. 1-1 at 6.) Ms. Shelp alleges that within a few months of her surgery, she developed several physical, muscular, and neurological symptoms caused by the breast implants. (*Id.* at 7.) In 2017, Ms. Shelp had surgery to remove the implants. (*Id.*) The doctor who performed that surgery found

[1] Plaintiffs have not filed a response to Mentor's motion to dismiss, which the Court can construe as an admission that the motion has merit. *See* W.D. Wash. Local Civ. R. 7(b)(2).

that scar tissue around the implants had tightened and caused the right implant to rupture. (*Id.*) The doctor determined that the implants were either "Allergan Natrelle silicone-filled gel breast implants and/or Mentor breast implants."[2] (*Id*.)

On June 1, 2018, Ms. Shelp and her husband filed a lawsuit in King County Superior Court against Mentor and several other Defendants. (*Id.* at 1.) The Shelps allege that Mentor's breast implants were negligently designed, and that Mentor knew or should have known of their "hazards and dangerous propensities" but failed to warn Ms. Shelp of those risks. (*Id.* at 9.) The Shelps allege causes of action for negligence, as well as violations of Washington State's products liability statute and Consumer Protection Act ("CPA"). (*Id.* at 10.)

On September 27, 2018, the case was removed to this Court. (Dkt. No. 1.) Mentor now moves to dismiss the claims against it. (Dkt. No. 20.) Like the Allergan Defendants, Mentor argues that all of the Shelps' claims are expressly preempted by the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act of 1938. (*Id*. at 2.)

II. DISCUSSION

A. Legal Standard

A defendant may move to dismiss claims against it where the complaint "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A complaint will survive a motion to dismiss if it contains factual allegations that, taken as true, state a plausible claim that the plaintiff is entitled to relief against the defendant. *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). When ruling on a motion to dismiss, the Court must accept as true all of the facts in the complaint, but will not draw unreasonable inferences from those facts or accept the validity of legal conclusions. *Vasquez v. Los Angeles County*, 487 F.3d 1246, 1249 (9th Cir. 2007).

Generally, the Court must decide a motion to dismiss based solely on the facts set forth in

[2] Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Allergan PLC (collectively the "Allergan Defendants") were also named as Defendants in this lawsuit. (See Dkt. No. 1.) The Court previously granted their motion to dismiss. (*See* Dkt. No. 19.)

the pleadings. *United States v. Corinthian Colls.*, 655 F.3d 984, 999 (9th Cir. 2011). However, the Court may take judicial notice of "matters of public record" not subject to reasonable dispute. Fed. R. Evid. 201. Thus, the Court may judicially notice the existence of a public record, as well as the record's content, so long as the content is not subject to reasonable dispute. *Lee v. City of Los Angeles*, 250 F.3d 668, 689–90 (9th Cir. 2001).

The Court takes judicial notice of the fact that the U.S. Food and Drug Administration ("FDA") granted premarket approval to Mentor for the breast implants allegedly at issue in this case on November 17, 2006. (Dkt. No. 20-2 at 3.) Premarket approval refers to the process by which the FDA grants permission for manufacturers to market certain medical devices after a rigorous testing process meant to ensure that the device is reasonably safe for use. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–20 (2008). The premarket approval for Mentor's Memorygel silicone gel-filled breast implants is documented in official, publicly available FDA records, the authenticity of which the Court finds is not subject to reasonable dispute.[3] *See Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1167 (9th Cir. 2012) (affirming district court's judicial notice of FDA's grant of premarket approval), *rev'd en banc on other grounds*, 704 F.3d 1224 (9th Cir. 2013).

B. Preemption under the MDA

The MDA expressly preempt state oversight of certain medical devices subject to FDA regulation. The relevant statute provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

[3] The FDA's letter granting premarket approval for Mentor's breast implants, as well as a summary of the implants' safety and effectiveness and FDA-approved labeling, is available on the FDA's website. *See U.S. Food & Drug Administration, Premarket Approval: Mentor MemoryGel Silicone Gel-Filled Breast Implants*, (Nov. 17, 2006), https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030053A.pdf.

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has set out a two-part test to determine if a state-law cause of action is preempted by the MDA. *Riegel*, 552 U.S. at 321–22. First, the Court must determine if federal law imposes "requirement[s] applicable to the device" at issue. *Id.* at 322. This showing is automatically satisfied where the FDA grants a device premarket approval. *Id.* If the first element is met, the Court must determine if a plaintiff's claims seek to impose state requirements "different from, or in addition to" the relevant FDA requirements. *Id.* State common-law duties are "requirements" within the meaning of the MDA. *Id.* at 324. Thus, in *Riegel*, the Supreme Court held that state common-law claims—including negligent design and failure to warn—are preempted in cases involving medical devices that receive premarket approval. *Id.* at 321–30. The Supreme Court concluded that such claims are preempted because, if successful, they would impose state safety requirements that are different from the FDA's requirements imposed through a premarket approval. *Id.* State-law claims that allege violations of FDA regulations, on the other hand, are not preempted. *Id.* at 330.

The Supreme Court's holding in *Riegel* applies to the Shelps' claims against Mentor. 552 U.S. 321–30. The FDA granted premarket approval for the Mentor breast implants allegedly at issue well before Ms. Shelp's breast augmentation surgery. (Dkt. No. 20 at 3–4.) Thus, federal law imposes requirements on those devices. *Riegel*, 552 U.S. at 322. The Shelps allege various state-law products liability claims, including that the breast implants were negligently designed and manufactured, as well as that Mentor failed to warn Ms. Shelp about the risks associated with using them. (*See* Dkt. No. 1-1.) The legal theory underlying the Shelps' CPA claim is not clearly stated, but because CPA claims require "an unfair or deceptive act or practice," the Court concludes that the Shelps base their CPA cause of action on Mentor's failure to warn Ms. Shelp about the dangers of using its product. *See Panag v. Farmers Ins. Co. of Wash.*, 204 P.3d 885,

889 (Wash. 2009). Nothing in the Shelps' complaint expresses or implies that the Mentor breast implant used by Ms. Shelp violated any FDA requirement. (*See generally* Dkt. No. 1-1.) Thus, like the plaintiffs in *Riegel*, the Shelps' claims seek to impose safety requirements on Mentor's breast implants that are both different from, and in addition to, the requirements imposed by the FDA's premarket approval. *See Riegel*, 552 U.S. 320–21. As a result, all of the Shelps' claims are expressly preempted by the MDA. 21 U.S.C. § 360k(a)(1).

III. CONCLUSION

For the foregoing reasons, the Defendant Mentor Worldwide LLC's motion to dismiss (Dkt. No. 20) is GRANTED. All of Plaintiffs' claims against Defendant Mentor Worldwide LLC are DISMISSED with prejudice.

DATED this 20th day of December 2018.

John C. Coughenour
UNITED STATES DISTRICT JUDGE